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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/775,768

02/10/2004

Antonios G. Mikos

01997/518004

8716

21559

7590

03/26/2007

CLARK & ELBING LLP  
101 FEDERAL STREET  
BOSTON, MA 02110

EXAMINER

NAFF, DAVID M

ART UNIT

PAPER NUMBER

1657

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/26/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/775,768

Applicant(s)

MIKOS ET AL.

Examiner

David M. Naff

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1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11 and 13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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#### DETAILED ACTION

A response of 12/19/06 submitted a request to correct inventorship under 37 CFR 1.48(a) along with a copy of papers filed in parent application 09/669,760 for the same change in inventorship, and  
5 amended claim 11 and canceled claim 12.

Claims examined on the merits are 11 and 13.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The date for *J. of Pediatric Surgery* on form 1449 of 6/23/05 has  
10 been changed to 1988.

In response to the request under 37 CFR 1.48(a), the inventorship will be changed as requested.

#### **Double Patenting**

Claims 11 and 13 are rejected on the ground of nonstatutory  
15 obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,689,608 B1 in view of Vacanti et al (5,759,830).

The polymeric matrix of the claims of the patent is the same as presently claimed except for matrix comprising cells as required by  
20 claim 11 and comprising a material enhancing cell attachment as required by claim 13.

Vacanti et al disclose attaching cells to a polymeric matrix. Different types of cells can be attached (col 6, lines 27-34), and the matrix can be coated with a coating that enhances cell attachment (col  
25 10, lines 43-48).

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Since the matrix of the patent claims is required by the claims to be suitable for attachment and proliferation of cells, it would have been obvious to attach to the matrix of the patent claims cells disclosed by Vacanti et al for attaching to a matrix. It would have been further obvious to coat the matrix of the patent claims with a cell attachment enhancing coating as disclosed by Vacanti et al to obtain the attachment enhancing function of the coating.

#### ***Double Patenting***

Claims 11 and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,514,378 in view of Vacanti et al (5,759,830).

It would have been obvious to attach cells to the membrane resulting from the process of the patent claims to obtain the function of cells attached to the membrane as suggested by Vacanti et al when attaching cells to a matrix since the membrane resulting from the method of the patent claims is biocompatible. Vacanti et al would have further suggested coating the membrane with a cell attachment enhancing coating as required by claim 13 to enhance cell attachment. The claims of the patent require a method for producing a porous biocompatible synthetic polymer membrane wherein crystallinity is modified (claim 2), the membrane has a porosity of greater than 90% (claim 9), and particles are used that will produce a pore size of 100-500 microns (claim 4). When modifying the crystallinity as claimed by claim 2 of the patent, it would have been obvious to select a preferred optimum degree of crystallinity of 0-24.5% as presently

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claimed. A membrane from the method of the patent claims having this crystallinity will be a matrix that is the same as the presently claimed matrix.

***Response to Arguments***

5 In response to the above double patent rejections, applicants indicate that terminal disclaimers will be filed.

***Conclusion***

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

10 A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the  
15 shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

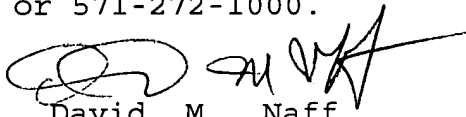
20 Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful,  
25 the examiner's supervisor, Jon Weber can be reached on 571-272-0925.

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The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
David M. Naff  
Primary Examiner  
Art Unit 1657

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DMN  
3/19/07